DOCKET NO: 241891US0CONT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :

Jean-Thierry SIMONNET, et al. : GROUP ART UNIT: 1612

SERIAL NO: 10/724,826 :

FILED: DECEMBER 2, 2003 : EXAMINER: MAEWALL, SNIGDHA

FOR: NANOEMULSION BASED ON SUGAR FATTY ESTERS OR ON SUGAR FATTY ETHERS AND ITS USES IN THE COSMETICS, DERMATOLOGICAL AND/OR OPHTHALMOLOGICAL FIELDS

DECLARATION UNDER 37 C.F.R. 1.132

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

I, Jean-Thierry Simonnet hereby declare:

1. I am employed by L'ORÉAL as an engineer and have experience in the field of measuring physical properties of cosmetic products.

2. The following observations and experiments were carried out by me or under my direct supervision and control.

3. The following compositions were prepared.

| INGREDIENT | COMPARATIVE COMPOSITION A | INVENTION COMPOSITION B | INVENTION COMPOSITION C |
|---|---|---|---|
| Methyl glucose sesqui-isostearate (Isolan IS) liquid at 45°C | 4.5% | | |
| Sucrose palmitostearate (mixture of mono-, di-, tri- and tetra- | | 4.5% | |

| | | | |
|---|---|---|---|
| esters) (Crodesta F70) solid at 45°C | | | |
| Sucrose palmitostearate (mixture of mono and polyesters) (Crodesta F50) solid at 45°C | | | 4.5% |
| Acylglutamate HS 21 (Ajinomoto) | 0.5 | 0.5 | 0.5 |
| Isopropyl myristate | 5 | 5 | 5 |
| Isocetyl stearate | 10 | 10 | 10 |
| Dipropylene glycol | 10 | 10 | 10 |
| Glycerol | 5 | 5 | 5 |
| Water | 32.5 | 32.5 | 32.5 |
| Water | 32.5 | 32.5 | 32.5 |

4. Comparative Composition A containing a liquid surfactant was prepared by homogenizing Isolan IS (A), Acylglutamate HS 21, isopropyl myristate and isocetyl stearate at a temperature of 45°C to prepare Phase 1. Then, dipropylene glycol, glycerin and water were mixed at temperature of about 25 °C to prepare Phase 2. The two phases were mixed together using a turbine homogenizer. Then homogenization was carried out using a high pressure homogenizer at a pressure of 1500bars, over 7 passages, the temperature of the product being maintained below 35°C.

5. Invention Compositions B and C containing solid surfactant were prepared according to the same protocol as above. The only difference was that the initial homogenization step was carried out at a temperature of 55°C to make sure that the solid surfactant became liquid.

6. The turbidity of compositions A-C above were determined using a Hach Model 2100 P portable turbidimeter at times $T_0$ (immediately), $T_1$ (after 1 month), and $T_2$ (after 2 months) at various temperatures. The results are presented in the table below.

| | | COMPARATIVE COMPOSITION A | INVENTION COMPOSITION B | INVENTION COMPOSITION C |
|---|---|---|---|---|
| T0 | T% / turb | 206 NTU | 239 NTU | 207 NTU |
| | Ø nm IP | Ø=50 nm IP0.03 | Ø=56 nm IP0.20 | Ø=46nm IP0.3 |
| T = 1 month | %T 4°C / turb. | 350 NTU | 247 NTU | 215NTU |
| | %T TA / turb. | 497 NTU | 229 NTU | 208NTU |
| | %T 37°C / turb. | 720 NTU | 223 NTU | 204NTU |
| | %T 45°C / turb. | 810 NTU | 214 NTU | 200NTU |
| | | **not stable T1 Month** | | |
| | | presence of crystals and increase size of the oily phase globules | **Stable** | **Stable** |
| | | | | |
| T = 2 months | %T 4°C / turb. | | 239 NTU | 214NTU |
| | %T TA / turb. | | 222 NTU | 209NTU |
| | %T 37°C / turb. | | 219 NTU | 204NTU |
| | %T 45°C / turb. | | 219 NTU | 204NTU |
| | | | **Stable** | **Stable** |

7. Comparative Composition A containing a liquid surfactant was unstable after 1 month -- crystals were present in the composition and the size of the oily phase globules had increased demonstrating composition instability. Moreover, the turbidity of the composition increased, particularly at increased temperatures. After 2 months, the composition was completely unstable, making turbidity measurements impossible.

8. In stark contrast, Invention Compositions B and C containing solid surfactant were stable, even after 2 months. Moreover, these compositions had low and stable turbidity characteristics, even at increased temperatures.

9. This vast difference in physical properties among Comparative Composition A and Invention Compositions B and C was surprising and unexpected given the similarity of the compositions. The improved stability and turbidity properties obtained with Invention Compositions B and C are representative of the present invention. That is, I would expect a nanoemulsion, comprising an oily phase dispersed in an aqueous phase and having oil globules with a number-average size of less than 100 nm, wherein the oil globules are free of a lamellar liquid crystal coating, a surfactant which is solid at a temperature of less than or

equal to 45EC, wherein the surfactant is selected from the group consisting of esters of a fatty acid and of a sugar and ethers of a fatty alcohol and of a sugar, and at least one oil having a molecular weight of greater than 400, wherein the ratio by weight of the amount of oily phase to the amount of surfactant is 2 to 10, to possess improved visual and viscosity properties like those of Invention Compositions B and C. I have no reason to expect otherwise.

10. The difference in physical properties between Comparative Composition A and Invention Compositions B and C demonstrates the surprising and unexpected benefit derived from using the required combination of ingredients in the Invention Compositions.

11. The improved stability and turbidity properties associated with the invention compositions would, of course, be commercially significant -- compositions containing such improved properties would be more appealing to consumers because, for example, more transparent (less turbid) products are generally perceived by consumers as being more pure and, thus, as being more desirable, and because stable products maintaining their original characteristics (and containing minimal crystals) over an extended period of time are also more desirable to consumers.

12. The undersigned petitioner declares further that all statements made herein of her own knowledge are true and that all statements made on information and belief are believe to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

13. Further deponent sayeth not.

_____

Name Jean Thierry Simonnet

Signature

Dec 5th, 2008

Date